UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UMB BANK, N.A., as Trustee, Plaintiff, v. SANOFI, Defendant.	:	Case No. 15 Civ. 8725 (GBD) (RWL) ECF CASE

SANOFI'S LOCAL RULE 56.1 STATEMENT

Pursuant to Rule 56.1 of the Local Civil Rules of the United States District Court for the Southern District of New York, Sanofi respectfully submits the following statement of the material facts as to which it contends there is no genuine issue to be tried.

I. The Parties

1. Plaintiff is a federally-chartered national banking organization with its principal place of business in Kansas City, Missouri, and is the "trustee of an express trust for the benefit of the [CVR] Holders." Second Amended Complaint ("Compl.") ¶¶ 9, 10.

2. Sanofi is a global pharmaceutical company organized under French law. *Id.* ¶ 11; Answer to Second Amended Complaint ("Answer") ¶ 11.

II. The Merger and the CVR Agreement

3. In connection with the negotiations relating to Sanofi's acquisition of Genzyme Corporation ("Genzyme"), the parties disagreed over the value of Genzyme, including, but not limited to, the value of Genzyme's product pipeline. Answer ¶ 181; Compl. ¶ 181.

4. Sanofi and Genzyme entered into a merger agreement dated February 16, 2011, pursuant to which Sanofi agreed to acquire Genzyme for $74 in cash and one publicly-traded contingent value right ("CVR") per Genzyme share. Answer ¶¶ 1, 3-4.

5. The terms of the CVRs are set forth in a Contingent Value Rights Agreement, by and between Sanofi and the predecessor trustee, American Stock Transfer & Trust Company, dated as of March 30, 2011 (the "CVR Agreement"). *Id*. ¶ 1; Compl. Ex. A (ECF No. 125-1).

6. UMB Bank, N.A. ("UMB") replaced American Stock Transfer & Trust Company as Trustee on July 19, 2016. Answer ¶¶ 4, 10.

7. On April 8, 2011, Sanofi completed its acquisition of Genzyme, with Genzyme surviving as a wholly-owned Sanofi subsidiary. That same day, the CVRs began trading on the NASDAQ under the ticker "GCVRZ." Answer ¶¶ 3-4.

8. As of December 31, 2018, a total of 236,457,284 CVRs was outstanding. Venezia Decl. Ex. M (Sanofi Form 20-F 2018 at 127).

III. The Terms of the CVR Agreement

9. Section 1.10 of the CVR Agreement provides, in pertinent part, that "the CVR Agreement and all claims or causes of action (whether in contract or tort) that may be based upon, arise out of or relate to this CVR Agreement . . . or the [CVRs], shall be governed by and construed in accordance with the laws of the State of New York." Compl. Ex. A (ECF No. 125-1) § 1.10.

10. The CVR Agreement contains five milestones related to Lemtrada -- the "Approval Milestone" and four separate "Product Sales Milestones." *Id*. § 1.1.

11. The CVR Agreement contains one milestone related to Cerezyme and Fabrazyme -- the "Production Milestone." *Id*.

12. CVR holders are entitled to a one-time cash payment if any of the milestones are achieved. *Id*.

13. Milestone payments to CVR holders under the CVR Agreement are not guaranteed. The CVR Agreement defines "Termination Date" as "the earlier of (a) December 31, 2020 and (b) the Payment Date for Product Sales Milestone #4." *Id.* §§ 7.10, 1.1.

14. The CVR Agreement states that Sanofi "shall use Diligent Efforts to achieve the Approval Milestone and the Product Sales Milestones, and shall use commercially reasonable efforts to achieve the Production Milestone on a timely basis." *Id*. § 7.10. The phrase "Diligent Efforts" is defined in the CVR Agreement; the phrase "commercially reasonable efforts" is not defined. *Id*. § 1.1.

15. Sanofi did not achieve the Approval Milestone, Product Sales Milestone #1, or the Production Milestone. Answer ¶¶ 18, 28.

IV. The Approval Milestone

16. In the United States, it is unlawful to introduce a drug into interstate commerce unless approved by the Food and Drug Administration (the "FDA") as safe and effective for a specific use. 21 U.S.C. § 355(a)-(b); 21 U.S.C. § 393; 42 U.S.C. § 262(a).

17. "Approval Milestone" is defined in the CVR Agreement as "receipt by the Company or one of its Affiliates, on or before March 31, 2014, of the FDA Approval of alemtuzumab for the treatment of multiple sclerosis." Compl. Ex. A (ECF No. 125-1) § 1.1.

18. "FDA Approval" is defined in the CVR Agreement as "the issuance by the FDA of a biologics license or a supplement to an existing biologics license for a product." *Id*.

19. Achievement of the Approval Milestone entitles a CVR holder to the "Approval Milestone Payment" of "one dollar ($1.00) per CVR." *Id*.

20. On November 14, 2014, the FDA approved Lemtrada for the treatment of patients with relapsing forms of multiple sclerosis. *Id.* ¶ 88; Venezia Decl. Ex. N (Nov. 14, 2014 Sanofi Press Release).

21. Sanofi did not achieve the Approval Milestone. Answer ¶¶ 18, 28.

V. Product Sales Milestone #1

22. "Product Sales Milestone #1" or "PSM#1" is defined in the CVR Agreement as "the first instance in which the sum of (x) the aggregate Major Market Product Sales for each Qualifying Major Market plus (y) the aggregate Product Sales achieved in all countries that are not Qualifying Major Markets during the four (4)-calendar quarter period that begins on the first anniversary of Product Launch equals or exceeds a total of four hundred million dollars ($400,000,000)." Compl. Ex. A (ECF No. 125-1) § 1.1.

23. Achievement of PSM#1 entitles a CVR holder to a "Product Sales Milestone Payment" of "two dollars ($2.00) per CVR." *Id.*

24. Sanofi did not achieve PSM#1. Answer ¶¶ 18, 28, 99.

VI. Production Milestone

25. The "Production Milestone" is defined in the CVR Agreement as:

> achievement of both of the following, at any time during the period starting on January 1, 2011 and ending on December 31, 2011 (and including, for the avoidance of doubt, for the time period on or after January 1, 2011 but prior to the consummation of the Merger, any production by Genzyme): (a) production and Release by the Company (or, in the case of the Allston manufacturing facility, by The Quantic Group) of a total of seven hundred thirty-four thousand, six hundred (734,600) 400 Unit Vial Equivalents of Cerezyme; and (b) production and Release by the Company (or, in the case of the Allston manufacturing facility, by The Quantic Group) of a total of seventy-nine thousand (79,000) 35-milligram Vial Equivalents of Fabrazyme.

Compl. Ex. A (ECF No. 125-1) § 1.1.

26. Achievement of the Production Milestone entitles a CVR holder to the "Production Milestone Payment" of "one dollar ($1.00) per CVR." *Id.*

27. Sanofi did not achieve the Production Milestone. Answer ¶¶ 28, 134-35.

28. On May 24, 2010, Genzyme entered into a Consent Decree with the FDA regarding the Allston Facility following FDA inspections at the Allston Facility that resulted in observations and a warning letter raising Current Good Manufacturing Practices deficiencies. *Id.* ¶ 157; Venezia Decl. Ex. M (Sanofi Form 20-F 2018 at 66). The Consent Decree was still in place during calendar years 2011 and 2012. Venezia Decl. Ex. M (Sanofi Form 20-F 2018 at 66).

Dated: New York, New York
September 13, 2019

John A. Neuwirth
Joshua S. Amsel
Stefania D. Venezia
Justin D. D'Aloia
Jessica N. Djilani
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, New York 10153
Tel: (212) 310-8000
Fax: (212) 310-8007

Attorneys for Sanofi